

## **REMARKS**

In the Office Action of May 21, 2008, the Examiner rejected claims 1, 3 and 11 under 35 U.S.C. § 103(a) for being obvious over Meierhoefer in view of Takanashi and Itoh.

Meierhoefer describes a vial in which a container body has a single layer made of a plastic.

Takanashi describes a medical container having an inner and outermost layer, each made of a polyolefin.

Itoh describes an impermeable container having an intermediate layer comprising a polycycloolefin layer. Specifically, Itoh only describes an intermediate layer comprising a copolymer of an olefin and a cycloolefin (see column 6, lines 40-47, Fig. 3, intermediate layer 12 and Example 1 of Itoh).

Independent claim 1 now recites that the intermediate layer is composed of “blends” of a polyolefin and a polycycloolefin. Support for this can be found in Example 4 at page 38 of the specification where the intermediate layer is a blend of a polycycloolefin and a polyolefin. See also Example 4 in Table 1 on page 41 of the specification.

As a result of this feature, a plastic ampoule having a smooth surface can be obtained. Therefore, the external quality of the plastic ampoule is improved by this feature.

In this regard, none of Meierhoefer, Takanashi or Itoh has any description or suggestion of the composition of the claimed intermediate layer, namely one composed of blends of a polyolefin and a polycycloolefin.

In support of applicants' position, enclosed is a Declaration of Mr. Yuki Manabe, that sets forth the results of experiments he conducted to evaluate the external quality of a plastic ampoule having an intermediate layer composed of a blend of a polyolefin and a polycycloolefin, with one composed of a copolymer of the olefin and the cycloolefin. In other words, with an intermediate layer as taught by Itoh.

As can be seen from the Declaration, it is clear that in Experiment 1 in which a blend of PE4 (a polyolefin) and COC3 (a polycycloolefin) was used as the intermediate layer, the plastic ampoule had a smoother surface and a superior external quality compared to the ampoule of Comparative Experiment 1 in which only COC3 (the copolymer of ethylene (olefin) and tetracyclododecene (cycloolefin)) is used as the intermediate layer.

Thus, not only does Itoh not disclose the intermediate layer claimed, but it cannot be considered to be an obvious variation of what is disclosed in view of the superior results achieved by it.

As required by MPEP § 2143.03, "all words in a claim must be considered in judging the patentability of that claim against the prior art" and it is apparent that none of the cited prior art shows the composition of the claimed intermediate layer. Also, as noted in MPEP § 2143.02, to support a conclusion that a claim would have been obvious, "all the claimed elements" must have been known in the prior art. Further, as noted in MPEP § 716.02(a), evidence of unexpected advantageous properties can rebut any prior facie case of obviousness. Thus, in view of the results shown in Mr. Manabe's Declaration, the claimed intermediate layer cannot be considered to be an obvious variant of the intermediate layer disclosed in Itoh.

Accordingly, for all of the above reasons, it is submitted that neither claim 1 nor claims 3 and 11 dependent therefrom can be considered obvious over the cited combination of references. Its withdrawal as a ground of rejection of these claims is therefore rejected.

The Examiner also rejected claims 4-7 and 12 over Meierhoefer, Takanashi and Itoh, further in view of Komatsu. However, since all of these claims depend from claim 1, it is submitted they are patentable over the cited references for the same reasons expressed above.

Finally, claims 13 and 15 were rejected under § 103(a) for being obvious over Louviere in view of Takanashi and Itoh. In response, claim 13 has also been amended, like claim 1, to recite that the intermediate layer is composed of blends of a polyolefin and a polycycloolefin. As noted by the Examiner on page 9, lines 10 and 11 of the Office Action, Louviere and Takanashi lack a disclosure of the claimed intermediate layer. While the Examiner believed this would be obvious in view of Itoh, for the reasons discussed above, including Mr. Manabe's Declaration, it is clear that the claimed intermediate layer is not obvious in view of Itoh.

Accordingly, it is believed claim 13 and claim 15 dependent therefrom are not obvious over the cited combination of references for the same reasons expressed above with respect to claim 1.

It is believed claims 1, 3-7 and 11-15 are in condition for allowance.

A Request for Continued Examination (RCE) is being filed with this Reply to enable the Examiner to consider the amended claims and Declaration of Mr. Manabe at this time.

If there are any fee due in connection with the filing of the Reply, please charge such fee to our deposit account 06-0916.

Respectfully submitted,

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**Attachments: Declaration of Mr. Yuki Manabe**

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